applicants submit the accompanying Declaration of Mme. Danielle Berneman. In view of this Declaration, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, are respectfully requested.

Claims 28, 29, and 32-38 are rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not reasonably enable the skilled artisan to make and/or use the invention commensurate in scope with the claims. The Examiner contends that the specification does not disclose, *ipsis verbis*, HIV/LAV viral clones or restriction fragments obtained from any other viral isolates, but that the claimed invention encompasses any HIV-1 DNA restriction fragment having the recited restriction sites. The Examiner further alleges that in view of the disclosures of Goodenow et al., Holland et al., and Gao et al., it would be reasonable for the skilled artisan to conclude that each HIV-1 viral isolate will display a unique genotype. In view of the foregoing, he concludes that it would not be readily manifest that other HIV-1 isolates will contain the same restriction sites disclosed in applicants' specification.

Applicants respectfully traverse this rejection. Claims 28, 29, and 32-38 are directed to compositions of DNA fragments of HIV-1 having particular restriction sites. Suppose the inventor who discovered aspirin, which he made by method A, filed a patent application with claims to the composition of aspirin. He would be entitled to a patent protecting that composition, regardless of where the aspirin came from. Whether the inventor purified the aspirin from a microorganism that secreted the product, or he used a chemical synthesis is irrelevant to the scope of protection afforded the composition.

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Likewise, the Applicants' claims encompassing DNA fragments of HIV-1 having particular restriction sites are entitled to protection regardless of where they come from. As long as a DNA fragment of HIV-1 has the claimed restriction sites, it is within the scope of the claim, and it should be protected.

Applicants reiterate that the Examiner has improperly relied on the disclosures of Goodenow et al., Holland et al., and Gao et al., which allegedly cast doubt on whether other HIV-1 isolates in addition to the LAV isolate, will contain the same restriction sites. These references were published after applicants' effective filing date, and therefore, the later discoveries of unknown variations cannot render the claims non-enabled. See In re Hogan, 194 U.S.P.Q. 527, 537 (C.C.P.A. 1977).

Applicants specification clearly discloses how the ordinarily skilled artisan can determine whether or not he was in possession of the claimed DNA fragments. The specification, at page 7, teaches using pLAV 13, a cDNA clone of LAV, in hybridization assays with LAV RNA from different sources. Applicants teach that LAV RNA was detected using the pLAV 13 as a probe when contacted with LAV from different sources, such as normal T cells, B-cell LAV- producing lines, CEM cells, and LAV from the bone marrow culture from a hemophiliac with AIDS.

The specification utilizes LAV as a tool for determining whether or not a DNA fragment had the claimed restriction sites. And, at the time the claimed invention was made, LAV was known as a standard experimental strain and model for HIV-1 isolates. Moreover, at the time of this application, one skilled in the art would have expected the results obtained from LAV to be

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generalizable across other HIV-1 strains. Therefore, at the time the claimed invention was made, the ordinarily skilled artisan could determine, without undue experimentation, whether or not a DNA fragment of any HIV-1 isolate contained the restriction sites claimed.

In view of the above, and since standard experimental models have often been recognized as supporting broader claims under 35 U.S.C. § 112, first paragraph, see e.g., In re Jolles, 206 U.S.P.Q. 885, 890-91 (C.C.P.A. 1980); In re Hartop, 135 U.S.P.Q. 419, 425-26 (C.C.P.A. 1962), applicants should not be limited to a DNA fragment of a particular strain of HIV-1. The mere fact that the compositions claimed may or may not come from other places is irrelevant.

In view of the foregoing remarks, applicants respectfully request withdrawal of the rejection.

Claims 28, 29, and 32-38 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicants regard as the invention.

The Examiner maintains that the recitation of "at approximately" precludes identification of the precise location of the restriction sites. Applicants again respectfully traverse this rejection.

Contrary to the rejection, "precise location" of the claimed restriction sites is not required. Applicants may allow for some experimental error by using such words as "substantially" or "approximately" without rendering the claim indefinite. In re Morosi, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983). Indeed, experimental variation is clearly evident from applicants'

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specification, wherein the coordinates of the successive sites of the whole LAV genomes were estimated to be within ±200 base pairs. Therefore, applicants respectfully submit that there is no better way of claiming the fragments of the invention. "While it is true that the word is not perfectly precise, under the circumstances of the present case there appears to be no other way for appellant to describe his discovery." In re Wilson, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970). In view of the foregoing remarks, applicants respectfully request withdrawal of the instant rejection.

Applicants submit that the foregoing remarks should overcome all outstanding rejections and place this application in condition for allowance.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Amendment, such extension is hereby requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge those fees to our Deposit Account No. 06-916.

Respectfully submitted,

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Dated: December 15, 1997

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